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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,284	04/21/2005	Eric Fredericus Bernardus Josephus Maria Thunnissen	13634PCTUS	1854

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EXAMINER	
WOOLWINE, SAMUEL C	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,284	THUNNISSEN ET AL.	
	Examiner	Art Unit	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☒ Claim(s) 1 and 4-9 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1 and 4-9 are objected to because of the following informalities: Each claim contains a period after each sub-step (i.e., a., b., i., ii., etc). MPEP 608.01(m) clearly states that each claim begins with a capital letter and ends with a period and that, "periods **may not be used elsewhere** in the claims ***except*** for abbreviations." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the recitation "amplification and labeling part of the E1 HPV gene, in particular its 3' end". This recitation renders claim 1 and therefore all claims vague and indefinite, because it is unclear whether the limitation "in particular its 3' end" is a requirement of the claim. It is also unclear if the claim means amplifying any part of the E1 gene, and labeling the 3' end of that part of the E1 gene, or whether the claim means amplifying the 3' end of the E1 gene, and labeling any part of that amplified product, or whether the claim means amplifying the 3' end of the E1 gene, and labeling the 3' end of that amplified product. It is also unclear as to what constitutes the 3' end of the E1 gene. Does this mean the amplification product or capture probe must contain

the very last (i.e. 3') nucleotide of the E1 gene? Or does this mean that anything 3' of the center nucleotide of the E1 gene is considered the 3' end? Or is anything 3' of the first (i.e. 5') nucleotide of the E1 gene considered the 3' end?

Based on the ambiguity of the claim, any part of the E1 gene will be considered part of the 3' end.

With regard to claim 2, it cannot be determined whether the recitation "first nucleic acid probes" refers to the "various HPV specific capture probes" of claim 1. Applicant is advised to clarify this issue. In addition, claim 2 recites "the glass support". There is insufficient antecedent basis for this limitation in the claim, because claim 1 only recites a solid support.

The examiner will assume the "first nucleic acid probes" of claim 2 refer to the capture probes of claim 1.

With regard to claim 3, it is unclear what is meant by "another HPV sequence". Does this mean the E1 amplification product or capture probes are "used" to detect multiple HPV variants, or that other HPV genes are amplified in addition the E1 gene, or that capture probes to other HPV genes in addition to the E1 gene are employed? Applicant is advised to more clearly indicate what is meant by "another HPV sequence" as well as how it is "used".

The examiner will assume that genes other than the E1 gene are amplified, and that capture probes derived from genes other than the E1 gene are present on the solid support.

With regard to claim 4, reciting the invention "as claimed in any one of claim 1" should simply recite "as claimed in claim 1". Similar correction should be made for claims 6-9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Manos et al (USPN 5,182,377).

With regard to claim 1, Manos teaches *a method of detecting the presence of HPV comprising*:

amplification and labeling part of the E1 HPV gene (see column 5, lines 40-45; column 8, line 34 through column 9, line 1; column 14, line 38 through column 15, line 30);

hybridizing the labeled fragment to a solid support containing microarrays with various HPV specific capture probes in the 3' end of the E1 region (see column 5, lines 40-45; column 8, line 34 through column 9, line 1; column 14, line 38 through column 15, line 30);

removing uncaptured labeled fragments (see for example column 7, lines 17-19; column 19, lines 1-3; washing removes uncaptured labeled fragments);

detecting captured detectable moiety indicating the presence of HPV sequence DNA in a sample (see for example column 8, lines 35-40; "determine whether a probe has hybridized to a DNA sequence").

With regard to claim 3, Manos teaches using E1 primers in conjunction with E6/7 primers (see column 15, lines 15-20).

With regard to claims 4 and 8, Manos teaches commercialization of his invention (see column 5, lines 64-68). This would have implied to one of ordinary skill in the art a "kit". Manos also teaches a PCR instrument (column 18, lines 13-14), a dot-blot apparatus (column 18, line 50), a water bath (column 18, line 57) and a shaker (column 19, line 3), all of which are devices suitable for carrying out the detection method according to claim 1. Manos teaches a number of primer sets (see for example Table 9, which shows E1 primer sets) and one or more solid supports (see column 8, line 34 through column 9, line 1).

With regard to claims 5 and 9, Manos teaches, for example, horseradish peroxidase (see column 9, lines 60-62), which is a reagent for signal enhancement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manos et al (USPN 5,182,377) in view of Fodor et al (USPN 5,925,525).

The teachings of Manos have been discussed above. Manos does not teach the solid support is a glass support upon which nucleic acid probes are printed, or building the probes on the support by light-directed oligonucleotide synthesis.

Fodor teaches building nucleic acid probes on a solid support using a light-directed synthesis (column 7, lines 36-40 and 45-51; column 38, lines 11-30). Fodor also teaches the substrate may be glass (column 46, lines 5-12).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to use solid supports comprising capture probes made by the method of Fodor when practicing the method of Manos, because Fodor states that his method reduces the number of manual manipulations required and automates most of the steps, providing for better speed, accuracy and reliability (column 2, lines 30-35).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

scw

3-19-07

YOUNG J. KIM
PRIMARY EXAMINER